

## **REMARKS**

### **I. Status of the Claims**

Claims 1-7 and 9-19 are pending in this case, with claim 1 being the sole independent claim. In the Office Action dated April 11, 2007, claims 1-6, 9-14, and 16-19 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,679,111 to Hjertman et al. ("Hjertman") and claims 7 and 15 were rejected under 35 U.S.C. § 103 as being obvious over Hjertman in view of U.S. Patent Application Publication No. 2002/0165499 A1 to Slate et al. The Office Action dated April 11, 2007 cites U.S. Patent Application Publication No. 2002/0167499 to Slate et al. (April 11, 2007 Office Action, Page 3). Applicant notes that U.S. Patent Application Publication No. 2002/0167499 A1 lists Bae et al. as inventors and is directed to a "Data Set-Up System for Display Device and Control Method Thereof." U.S. Patent Application Publication No. 2002/0165499 A1 to Slate et al. ("Slate") was referenced in an Office Action dated August 11, 2006, accordingly, Slate will be used for these remarks. Applicant requests the Examiner's clarification if the above understanding concerning Slate is incorrect. These rejections are traversed for the reasons set forth below.

### **II. Claim 1 is Not Anticipated by Hjertman**

Independent claim 1 recites a drive mechanism comprising, *inter alia*, a housing having internal and external threads, a piston rod threadedly engaged with the internal thread of the housing, a drive sleeve located between the housing and the piston rod, and clutch means located between the drive sleeve and the dose dial sleeve.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." M.P.E.P.

§ 2131, quoting *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Furthermore, “[t]he identical invention must be shown in as complete detail as is contained in the . . . claim.” See M.P.E.P. § 2131, quoting *Richardson v. Suzuki Motor Co.*, 868 F.2d 1126, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Finally, “[t]he elements must be arranged as required by the claim.” M.P.E.P. § 2131.

Rejecting claims 1-6, 9-14, and 16-19, the Office Action of April 11, 2007 alleges that:

Hjertman discloses a device for dosing a liquid preparation comprising a housing 3 having internal and external threads, a piston rod 12, a coupling 7, a dose dial sleeve 2, a drive sleeve 17, and a clutch sleeve 15. See Fig. 1. Hjertman inherently discloses the steps of providing the drive mechanism above. The device may be used to inject a patient with insulin (Col. 3, lines 16-17).

(April 11, 2007, Office Action, Page 2). The reference numbers from Hjertman indicated in the Office Action, however, do not correspond to the particular features recited in claim 1.

For example, regarding the piston rod of claim 1, the Office Action refers to the piston rod 12 of Hjertman. The piston rod recited in claim 1 includes the limitation of being threadedly engaged with the internal threads of the housing. Therefore, the piston rod 12 of Hjertman cannot correspond to the claimed piston rod at least because element 12 of Hjertman is not threadedly engaged with element 3 of Hjertman, which the Office Action relies upon as corresponding to the claimed housing.

Moreover, the piston rod 12 of Hjertman includes no threading engagement with any other feature. To the contrary, instead of threadingly engaging a housing, in the

arrangement of Hjertman, the piston rod 12 is merely displaced by action of compression spring 32. The pressure from compression spring 32 displaces piston rod 12, which then displaces piston 11 to force expulsion of liquid from cartridge 6. (See, e.g., Hjertman at column 6, lines 29 - 48 and FIG. 1). Accordingly, for at least the reasons presented above, item 12 of Hjertman cannot be relied upon as corresponding to the claimed piston rod.

In addition, the Office Action relies on interior sleeve 7 as corresponding to the claimed "unidirectional coupling" of claim 1. (April 11, 2007 Office Action, Page 2). Interior sleeve 7 is not a unidirectional coupling as recited in claim 1 as properly viewed in light of the current specification and thus cannot be relied upon as corresponding to this feature of claim 1. For example, nothing about the interior sleeve causes unidirectional coupling in the device of Hjertman. Furthermore, the Office Action points to a front sleeve 2 of Hjertman as corresponding to a "dose dial sleeve 2." (April 11, 2007 Office Action, Page 2). The front sleeve 2 of Hjertman is joined to rear sleeve 1 and sleeve 3 to hold an injection cartridge 6. (See, e.g., Hjertman at column 4, lines 10 - 18 and FIG. 1). Thus, front sleeve 2 does not have any function with respect to dose dialing and therefore it cannot be relied upon to correspond to a dose dialing sleeve as recited in claim 1.

The Office Action further alleges that actuation sleeve 17 of Hjertman corresponds to "a drive sleeve 17." (April 11, 2007 Office Action, Page 2). Since the actuation sleeve 17 merely serves to assist the action of lugs 14 and upright stalks 15 to lock the piston rod 12 (see, e.g., Hjertman at column line 50 to column 5 line 3), actuation sleeve 17 therefore cannot be relied upon as corresponding to a drive sleeve.

Furthermore, the Office Action points to upright stalks 15 of Hjertman as corresponding to “a clutch sleeve 15.” (April 11, 2007, Office Action, Page 2). Applicant assumes that the Examiner is alleging that the upright stalks 15 of Hjertman somehow correspond to the recited clutch means of claim 1. As required in claim 1, the clutch means must be located between a drive sleeve and the dose dial sleeve (which the Office Action alleges as corresponding to items 17 and 2 of Hjertman, respectively). The upright stalks of Hjertman cannot correspond to the claimed clutch means at least because item 15 is not located between items 17 and 2 of Hjertman, which the Office Action relies on as corresponding to the claimed drive sleeve and the dose dial sleeve, respectively. Instead, as seen in figure 1 of Hjertman, item 15 is located inwardly of, and not between, both the actuating sleeve 17 (allegedly corresponding to the claimed drive sleeve) and the sleeve 2 (allegedly corresponding to the claimed dose dial sleeve).

Finally, independent claim 1 requires a clutch means to allow or prevent relative rotational movements of the dose dial sleeve and the drive sleeve. In light of the current specification, a clutch means connects the dose dial sleeve and the drive sleeve. (See, e.g., specification at page 12). At most upright stalks 15 of Hjertman connect the piston rod 12 to the interior sleeve 7 (see, e.g., Hjertman at column 4 lines 34-49) and merely allow or prevent linear movement of piston rod 12. Therefore, upright stalks 15 cannot be relied upon to correspond to a clutch means as required by independent claim 1. Upright stalks 15 play no role in preventing or facilitating rotation of sleeve 2 in Hjertman (which was relied upon by the Examiner as corresponding to the claimed dosage dial sleeve).

Accordingly, for at least the reasons presented above, Hjertman cannot anticipate independent claim 1. Therefore, Applicant respectfully requests that the rejection of independent claim 1 and its dependent claims 2-6, 9-14, and 16-19 be withdrawn.

### **III. Claim Rejections - 35 U.S.C. § 103(a)**

As noted above, the Examiner rejected claims 7 and 15 under 35 U.S.C. § 103(a) as being unpatentable over Hjertman in view of Slate. A claim is obvious "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (2000). Two of several factual inquiries underlying this determination are the scope and content of the prior art and the differences between the claimed invention and the prior art. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

In determining the differences between the claimed invention and the prior art, the proper analysis under § 103(a) must consider the invention as a whole and not simply the differences themselves. See, M.P.E.P. § 2141.02 (8<sup>th</sup> ed. 2001, Rev. August 2006), p. 2100-121 - 2100-122. Moreover, all the claim limitations must be taught or suggested by the prior art. *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1970) ("All words in the claim must be considered in judging the patentability of that claim against the prior art."). The initial burden of establishing a *prima facie* case of obviousness is on the Examiner.

As noted above in the discussion of the Section 102 rejections, Hjertman fails to teach each of the recitations of independent claim 1. Regarding the Section 103

rejections, the Office Action does not rely on Slate to cure the above-noted deficiencies of Hjertman. Further, Slate does not remedy these deficiencies. A *prima facie* case of obviousness therefore has not been established with regard to any of the pending claims. For at least these reasons, Applicants request that the rejections under 35 U.S.C. § 103(a) be withdrawn.

**CONCLUSION**

In view of the foregoing remarks, this claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application. Applicants therefore respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims. Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,  
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